

REMARKS

Claims 1, 4 and 5 are pending in this application. By this Amendment, claim 1 is amended and claims 2, 3, 6 and 7 are canceled.¹ Support for the amendments to claim 1 may be found, for example, in original claims 2 and 3. No new matter is added. In view of the foregoing amendments and following remarks, reconsideration and allowance are respectfully requested.

I. Rejection Under 35 U.S.C. §112

The Office Action rejects claims 1-6 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description and enablement requirements. By this Amendment, claims 2, 3 and 6 are canceled, thereby rendering their rejection moot. As to the remaining claims, the rejection is respectfully traversed.

A. Written Description

Contrary to the Office Action's allegation on page 2 that the claims contain "subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention," the specification, in paragraphs [0011], [0012], [0019] and [0028] provides written description for the subject matter of the pending claims.

A description as filed is presumed to be adequate, unless or until the Office Action presents sufficient evidence or reasoning to the contrary to rebut the presumption. MPEP §2163.04, citing *In re Marzocchi*, 439 F.2d 220, 224 (CCPA 1971). The Office Action has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the

¹ Page 1 of the Office Action indicates that claims 1-6 are pending. However, this appears to be a typographical error, as claims 1-7 were pending in this application as of the April 1, 2008 mailing date of the present Office Action.

claims. MPEP §2163.04, citing *In re Wertheim*, 514 F.2d 257 at 263 (CCPA 1976). In view of the ample written description in the present specification, the Office Action has not established by a preponderance of evidence why a person skilled in the art would not recognize in the present specification a description of the subject matter of the pending claims.

Paragraph [0011] of the present specification describes that vitamin C undergoes autoxidation to release radicals. A large amount of vitamin C complexes to copper by chelation and the complex produces a potent active oxygen radical. Paragraph [0012] describes that during parasitism, a virus invades a cell, and the viral nucleotide "escapes from its outer shell (envelope) and inner shell (protein layer) and becomes a naked DNA or RNA." The active oxygen radical produced by vitamin C and copper cleaves the naked nucleotide sequence, thereby inactivating the virus. Upon completion of parasitism, the virus escapes out of the infected cell to invade another cell. After escaping out of the cell, the naked DNA or RNA is attacked by the active oxygen radical. These attacks *kill the virus to prevent an infection*. Paragraph [0013] further describes that vitamin C also helps to restore the body from a peroxidized condition to a normal reduced condition. Paragraph [0019] describes that arginine reinforces and assists the action of vitamin C. Paragraphs [0015], [0016] and [0021] describe suitable amount in which the vitamin C and arginine can be administered according to the present claims. Paragraph [0028] describes that the "present invention can prevent infection of a wide variety of viruses...[including] severe acute respiratory syndrome (SARS)." Accordingly, the specification provides ample written description to support the subject matter of the pending claims.

The Office Action, on page 2, attempts to establish unpredictability in the prevention of viral infection art by citing paragraph [0004] of the present specification and erroneously concluding that "preventing viral infection is very unpredictable and [the] only known method

for preventing viral infection is vaccination." However, this statement is unsubstantiated on two grounds.

First, paragraph [0006] of the present specification describes another method for preventing viral infection: "To inhibit viral infection *without the use of vaccine*, for example, a technique of administering...a sufficient amount of serine leucocyte protease inhibitor, an analogue thereof or a derivative thereof to prevent infection is known." This "technique is efficacious for infectious diseases induced by retrovirus, such as cancer and autoimmune diseases, and can be preferably used as a countermeasure against infection" of HIV virus, such as AIDS (emphasis added). See paragraph [0006]. Therefore, contrary to the Office Action's assertion, vaccination is *not* the only method for preventing viral infection.

Second, paragraphs [0004] and [0005] state that the "prevention of viral infection by such a *vaccine* is, however, not universal" and the use of "vaccination has serious restrictions" (emphasis added). Therefore, the present specification discusses the shortcomings of only one specific method of preventing viral infections. Having previously established that vaccination is not the only method of preventing viral infection, the Office Action's attempt to establish unpredictability in the viral infection prevention art by making a broad assertion that "preventing *viral infection* is very unpredictable" based on the description of one disclosed method of preventing viral infection is unsubstantiated (emphasis added).

Accordingly, because the specification provides sufficient written description for the subject matter of the pending claims, reconsideration and withdrawal of the rejection are respectfully requested.

B. Enablement

Contrary to the Office Action's allegation on page 3 that the claims contain "subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the

invention," the specification is fully enabling for the subject matter of the pending claims. As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement is satisfied. MPEP §2164.01, citing *In re Fisher*, 427 F.2d 833, 839 (CCPA 1970).

The specification is fully enabling for the subject matter of the pending claims, and it discloses at least one method for making and using the subject matter of the pending claims. Paragraphs [0015], [0016] and [0026] of the present specification describe that in order to prevent viral infection, a daily dose of vitamin C can be administered via a liquid drip infusion, injection, or oral administration in an amount of "at least 300 to 500 mg/kg/day (20 g or more per day)" and up to a "maximal amount at which vitamin C can be taken orally without inducing uncomfortable diarrhea, and is about 4 to 15 g per day in a normal human subject." The maximal permissible dose may exceed 200 g/day in some subjects suffering from a severe disorder. The actual amount administered is determined by routine experimentation by one of ordinary skill in the art, by taking into account various factors, such as age, weight, gender and overall health, of a subject. Paragraph [0017] describes that "for oral administration, it is convenient to dissolve the necessary amount of vitamin C in about 2 liters of a beverage such as a juice and drink it in about ten installments. Vitamin C is preferably dissolved each time immediately before administration, because 50% of vitamin C once dissolved in a juice becomes an oxidized derivative within about 90 minutes and its effects decrease." Paragraph [0017] further describes that "in the administration of vitamin C by drip infusion, pH of the drip infusion must be controlled at around 6.5. The activity of vitamin C decreases if the drip infusion has a pH of 7.0 or greater." Paragraph [0018] describes that arginine is "administered together with a high dose of vitamin C according to the prevention method of the present invention." Paragraph [0021] describes that "the dose of

arginine is generally 3 g/day or more," but can vary depending on various factors, such as weight, gender, age and health, of the subject. Furthermore, paragraph [0021] describes that "if a desired effect is not obtained at a dose of 3 g/day, the dose can be increased, for example, to 6 g/day, and further to 9 g/day."

Accordingly, the specification provides ample guidance for one of ordinary skill in the art to make and use the subject matter of the pending claims. Therefore, reconsideration and withdrawal of the rejections are respectfully requested.

II. Rejection Under 35 U.S.C. §103

The Office Action rejects claim 6 under 35 U.S.C. §103(a) as allegedly having been obvious over Paul in view of Yoshimura and further in view of Koff. By this Amendment, claim 6 is canceled, thereby rendering its rejection moot. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

III. Conclusion

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of this application are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



James A. Oliff
Registration No. 27,075

Hee H. Smith
Registration No. 57,631

JAO:HHS/mef

Date: July 1, 2008

OLIFF & BERRIDGE, PLC
P.O. Box 320850
Alexandria, Virginia 22320-4850
Telephone: (703) 836-6400

<p>DEPOSIT ACCOUNT USE AUTHORIZATION Please grant any extension necessary for entry; Charge any fee due to our Deposit Account No. 15-0461</p>
